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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,768	10/09/2001	Kenneth C. Cundy	033053-040	6895

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,768

Applicant(s)

CUNDY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,7,10-17,19,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,9,18,20 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2002 & 8/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

First Office Action on the Merits

Election/Restrictions

1. Applicant's election with traverse of the compound identified in the reply filed on December 20, 2004 is acknowledged. The traversal is on the ground(s) that the structure of the drug is not the patentable aspect of the claimed compounds. According to applicant, the patentable portion of the compounds of formula (I) is that portion of the compounds up to D'. This is not found persuasive because the portion of the compounds up to D' is known in the art and, thus, the patentability of the compounds is based on the addition of a drug, D', as defined by the claimed invention (see for example, RN 205588-97-2, which differs from the elected species only in that which is attached to phenylalanine, i.e., D').

2. For the record, in the present application, the instant invention will be searched to the extent it reads on the elected Group defined by applicant in the reply filed December 20, 2004. That is, compounds of formula (I) and compositions thereof, wherein R^1 and R^2 are independently hydrogen or hydroxyl; X is hydroxyl; Z is $-M-Q^x$ wherein M is $-CH_2CH_2C(O)-$ and Q^x is $-I^j-J^j-D'-K^k-R^{40'}$ wherein j and k are zero; I^j is $[NR^{50'}-(CR^{51'}R^{52'})_a-(CR^{53'}R^{54'})_b-C(O)]$, wherein one of a or b is 1 and the other is zero (i.e., an α -amino acid) and $R^{40'}$ is hydroxyl. However, D' was searched to the extent it reads on drugs, including ampicillin, containing a heterocyclic ring system and at least one carboxylic acid group as set forth by the present specification.

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3. Based on applicant's elected Group, claims 2, 5, 7, 10-17, 19, 21 and 22 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1, 3, 4, 6, 8, 9, 18, 20 and 23 will be searched to the extent they read on Group defined above #2.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 4, 6, 8, 9, 18, 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims is indefinite for the following reasons:

(a) Claims 1 and 18 recite, for example, "a drug containing at least one carboxylic acid group and at least one moiety selected from the group consisting of a primary amino group, a secondary group or a hydroxyl group" however, the instant claims also proviso out a variety of different classes of compounds, for example, a GABA analog, L-Dopa, an L-aromatic amino acid decarboxylase inhibitor etc. Thus, apart from the specific compounds set forth in the present specification, it is unclear what said drug is;

(b) Claims 1 and 18 recite "Z is..... -OSO₃H and **the like**..." . The present specification does not define what is intended by the phrase "the like" and, thus, the scope of the claimed invention is unclear;

(c) Claim 3 recites "Z is a substituted alkyl group of the formula –M-Q^x" however, parent Claim 1 does not recite said limitation;

(d) Claim 8 recites "g', h', m', n', o' and p'" but does not identify said variables in the instant claim or the parent claim and

(e) Claim 9 recites the variable Q^x but does not identify or define said variable in said claim or parent claim 1.

For the reasons given above, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 18 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada (JP 11-60594).

Okada teaches bile acid derivatives useful as nasal absorbefacient (see the entire article, especially page 8, compound #s 1-67, 1-68, 1-71, 1-72, 1-75, 1-76, 1-79, 1-80, 1-83, 1-84, 1-87 and 1-88). The compounds and compositions taught by the reference are encompassed by the instant claims.

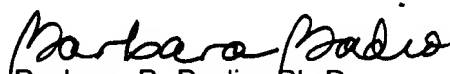
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Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
February 7, 2005